

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Shlomo Raz, Los Angeles, CA

Anticipated Group Art Unit: 3738

Motti Beyar, Caesarea, ISRAEL

Oren Globberman, Herzelia, ISRAEL

Serial No. Unknown

Filed: July 23, 2003

Anticipated

Examiner: Matthews

For: Method and Apparatus For Correction of Urinary and Gynecological Pathologies,
Including Treatment of Male Incontinence, and Female Cystocele

PRELIMINARY AMENDMENT

Commissioner for Patents
Alexandria, VA 22313-1450

Dear Sir:

Prior to a first action on the merits, please amend the application as follows:

In the Specification:

On page 1, after the title, please replace:

Inventors: Shlomo Raz

Motti Beyar

Oren Globberman

with:

This is a divisional of U.S. Application No. 10/252,179, filed on September 23, 2002 which is a divisional of U.S. Application No. 09/748,963, filed on December 27, 2000, now U.S. Pat. No. 6,502,578, which is a continuation of U.S. Patent Application No. 09/296,735, filed April 22, 1999, now U.S. Pat. No. 6,382,214, which was a non-provisional of provisional application no. 60/082,905, filed April 24, 1998.

On page 3, lines 11-22 and

page 4, lines 1-2, please replace the paragraph with:

In another embodiment of the invention, an especially flat shaped balloon is positioned between the sling material and the urethra to provide desired compression. Examples of inflatable balloon devices are disclosed in U.S. Patent entitled Systems for Percutaneous Bone and Spinal Stabilization, Fixation and Repair, (U.S. Pat. No. 6,127,597), filed Mar. 6, 1998 by Mordechai Beyar, Oren Globberman and Elad Magal, the disclosure of which is fully incorporated herein by reference. This balloon is inflated with fluid, and the volume can be adjusted by inflation or reduction of the fluid inside the balloon, using a tiny needle inserted through the perineal area. In a further embodiment of the invention, the sling material is part of the flat balloon. The sling material and the balloon can be either be an integral single unit, or the sling material can be attached or secured to the balloon. Inflation and deflation of the balloon, in conjunction with the sling (which is preferably secured using suitable bone anchors and suture), is used to correct the urinary pathology, in accordance with the methods disclosed herein. The sling is attached to the bone by means of bone anchors.

On page 10, lines 12-21 and

page 11, line 1 please replace the paragraph with:

In accordance with the present invention, a T-Sacrospinous fixation procedure is further provided herein, as shown in FIG. 11. A T-anchor™ is threaded with suture and loaded onto the anchoring device of FIG. 3. With the patient under anaesthesia and in the lithotomy position, the surgical area and the vagina are disinfected. The posterior vaginal wall is opened, the rectum is pushed to the left, and the sacrospinous ligament is palpated. Palpating the ligament with a finger, the inserter is advanced along the finger until the tip of the anchor perforates the sacrospinous ligament. The insertion lever is then pressed (after disengaging the safety), causing the anchor to be deployed in the sacrospinous ligament, resulting in a firm attachment to the ligament. The inserter is then pulled out, and the suture is pulled for proper anchoring as disclosed above. The procedure is then repeated on the contralateral side. Colporrhaphy is then performed.

On page 11, lines 2-6, please replace the paragraph with:

In accordance with additional inventions of the present application, a variety of further surgical procedures using bone screws to correct urological and gynecological pathologies are further disclosed below. The disclosures of U.S. Patent Application Ser. No. 08/804,172 (filed Feb. 21, 1997) and U.S. Pat. No. 6,334,446, relating to bone anchors and inserters, including bone screw and screw inserters, are fully incorporated herein by reference.

On page 16, lines 1-4, please replace the paragraph with:

At the deepest point of the vagina, one free end of the suture is used for threading through a good sized portion of vaginal wall, and the end is then transferred to the vaginal lumen. Then the other end of the suture is likewise also transferred to the vaginal lumen, at a distance of approximately 1 to 2 cm from the prior suture.

On page 22, lines 8-15, please replace the paragraph with:

This surgery is similar to the enterocele repair. A vertical incision is made over the posterior and superior vaginal wall. The dissection is carried out laterally to enter the extraperitoneal pararectal space, toward the coccygeus muscle (above levators, beneath peritoneum and lateral to the rectum). The sacrospinous ligament is felt as it attaches to the ischial spine. Two fascial anchors are applied 2-3 cm medial from the spine. The end of the sutures is used to anchor the vaginal wall in a similar fashion, as described above. After closing the vaginal wall, the sutures are tied, making sure that the vaginal wall slides easily to the anchoring point.

A version marked up to show changes made to the specification relative to the previous version of the specification is attached.